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<p>(21) International Application Number: PCT/US98/09634</p> <p>(22) International Filing Date: 12 May 1998 (12.05.98)</p> <p>(30) Priority Data: 08/856,902 15 May 1997 (15.05.97) US</p> <p>(71) Applicant (for all designated States except US): SDGI HOLDINGS, INC. [US/US]; Suite 508, 300 Delaware Avenue, Wilmington, DE 19801 (US).</p> <p>(72) Inventors; and (75) Inventors/Applicants (for US only): FARRIS, Robert, A. [US/US]; 981 Robin Hood Lane, Memphis, TN 38111 (US). POYNER, Jeffrey, Wade [US/US]; 234 Oxford Drive, Atoka, TN 38004 (US). SONNTAG, Volker, K., H. [US/US]; 5202 East Exeter Boulevard, Phoenix, AZ 85018 (US). HAID, Regis, W., Jr. [US/US]; 2995 Devonshire Place, Atlanta, GA 30327 (US). PAPADOPOULOS, Stephen, M. [US/US]; 2465 Adare Road, Ann Arbor, MI 48109 (US).</p> <p>(74) Agents: REEVES, Charles, R. et al.; Woodard, Emhardt, Naughton, Moriarty &amp; McNett, Bank One Center/Tower, Suite 3700, 111 Monument Circle, Indianapolis, IN 46204 (US).</p>		<p>(81) Designated States: AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, CA, CH, CN, CU, CZ, DE, DK, EE, ES, FI, GB, GE, GH, GM, GW, HU, ID, IL, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MD, MG, MK, MN, MW, MX, NO, NZ, PL, PT, RO, RU, SD, SE, SG, SI, SK, SL, TJ, TM, TR, TT, UA, UG, US, UZ, VN, YU, ZW, ARIPO patent (GH, GM, KE, LS, MW, SD, SZ, UG, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, ML, MR, NE, SN, TD, TG).</p> <p><b>Published</b> Without international search report and to be republished upon receipt of that report.</p>
<p>(54) Title: ANTERIOR CERVICAL PLATING SYSTEM</p> <div data-bbox="337 1163 1284 1646"> </div> <p>(57) Abstract</p> <p>In one embodiment of the invention, an anterior fixation system (30) includes a plate (31a-31g) defining a plurality of screw holes (34), a number of screws (32) and a number of locking assemblies (33) for fixing the screws (32) to the plate (31a-31g). The system (30) includes two bone screws (32), a fixed angle screw (50) and a variable angle screw (60). Either the fixed or variable angled screws (50, 60) may be implanted with a single plate (31a-31g), and either type of screw (50, 60) may be placed into any of the screw holes (34) along the plate (31a-31g). The several screw holes (34) may be in various patterns (38, 39, 40, 41, 42, 43, 44). The invention further contemplates a locking assembly (33) to lock one or more bone screws (32) within a respective screw hole (34). In one embodiment, the locking assembly (33) includes a washer (90) overlapping one or more screw holes (34), and a locking screw (85). In another embodiment, a locking washer (120) includes cut-outs (128) corresponding to the screw recesses (105), along with a notch (110) and key (129) configuration.</p>		

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## ANTERIOR CERVICAL PLATING SYSTEM

### BACKGROUND OF THE INVENTION

The present invention concerns spinal instrumentation systems, most particularly for use in fixation of the cervical spine. More particularly, the invention pertains to a plating system for use in the treatment of various spinal pathologies.

As with any bony structure, the spine is subject to various pathologies that compromise its load bearing and support capabilities. The spine is subject to degenerative diseases, the effects of tumors and, of course, fractures and dislocations attributable to physical trauma. Throughout the last century, spinal surgeons have tackled the thorny problems associated with addressing and correcting these pathologies using a wide variety of instrumentation and a broad range of surgical techniques. For many years, the use of elongated rigid plates has been helpful in the stabilization and fixation of the lower spine, most particularly the thoracic and lumbar spine. These same plating techniques have found a tougher road towards acceptance by surgeons specializing in treatment of the cervical spine.

The cervical spine can be approached either anteriorly or posteriorly, depending upon the spinal disorder or pathology to be treated. Many of the well known surgical exposure and fusion techniques of the cervical spine are described in a publication entitled *Spinal Instrumentation*, edited by Drs. Howard An and Jerome Cotler. This text also describes instrumentation that has been developed in recent years for application to the cervical spine, most frequently from an anterior approach.

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The anterior approach to achieving fusion of the cervical spine has become the most popular approach. During the early years of cervical spine fusion, the fusions occurred without internal instrumentation, relying instead upon external corrective measures such as prolonged recumbent traction, the use of halo devices or minerva casts, or other external stabilization. However, with the advent of the elongated plate customized for use in the cervical spine, plating systems have become predominant for this type of spinal surgery.

It has been found that many plate designs allow for a mono-cortically or bi-cortically intrinsically stable implant. It has also been found that fixation plates can be useful in stabilizing the upper or lower cervical spine in traumatic, degenerative, tumorous or infectious processes. Moreover, these plates provide the additional benefits of allowing simultaneous knurled decompression with immediate stability.

During the many years of development of cervical plating systems, particularly for the anterior approach, various needs for such a system have been recognized. For instance, the plate must provide strong mechanical fixation that can control movement of each vertebral motion segment in six degrees of freedom. The plate must also be able to withstand axial loading in continuity with each of the three columns of the spine. The plating system must be able to maintain stress levels below the endurance limits of the material, while at the same time exceeding the strength of the anatomic structures or vertebrae to which the plating system is engaged.

Another recognized requirements for a plating system is that the thickness of the plate must be small to lower its prominence, particularly in the smaller spaces of the cervical spine. The screws used to connect the plate to the vertebrae must not loosen over time or back out from the

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plate. Preferably the plate should be designed to contact the vertebrae for greater stability.

On the other hand, while the plate must satisfy certain mechanical requirements, it must also satisfy certain  
5 anatomic and surgical considerations. For example, the cervical plating system must minimize the intrusion into the patient and reduce the trauma to the surrounding soft tissue. In the *Spinal Instrumentation* text, as well as in  
10 other documentation in this field, it is stressed that complications associated with any spinal procedure, and most particularly within the tight confines of cervical procedures, the complications can be very devastating, such as injury to the brain stem, spinal cord or vertebral arteries. It has also been found that optimum plating  
15 systems permit the placement of more than one screw in each of the instrumented vertebrae.

Many spinal plating systems have been developed in the last couple of decades that address some of the needs and requirements for cervical fixation systems. However, even  
20 with the more refined plating system designs, there still remains a need for a system that has universal applicability to all pathologies that can be faced by a spinal surgeon in treating the spine. For example, it has been demonstrated that different degrees of fixation of a bone screw relative  
25 to the plate are more advantageous for treating certain pathologies as opposed to other pathologies.

More specifically, it is known that bone screws can be supported in a spinal plate in either a rigid or a semi-rigid fashion. In a rigid fashion, the bone screws are  
30 not permitted any micro-motion or angular movement relative to the plate. In the case of a semi-rigid fixation, the bone screw can move somewhat relative to the plate during the healing process of the spine. It has been determined that semi-rigid fixation is preferable for the treatment of  
35 degenerative diseases of the spine. In cases where a graft

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is implanted to replace the diseased vertebral body, the presence of a screw capable of some rotation ensures continual loading of the graft. This continual loading avoids stress shielding of the graft, which in turn  
5 increases the rate of fusion and incorporation of the graft into the spine.

Similarly, rigid screw fixation is believed to be preferable in the treatment of tumors or trauma to the spine, particularly in the cervical region. It is believed  
10 that tumor and trauma conditions are better treated in this way because the rigid placement of the bone screws preserves the neuro-vascular space and provides for immediate stabilization. It can certainly be appreciated in the case of a burst fracture or large tumorous destruction of a  
15 vertebra that immediate stabilization and preservation of the disc space and neuro space is essential. On the other hand, the semi-rigid fixation is preferable for degenerative diseases because this type of fixation allows for a dynamic construct. In degenerative conditions, a bone graft is  
20 universally utilized to maintain either the disc space and/or the vertebral body itself. In most cases, the graft will settle or be at least partially resorbed into the adjacent bone. A dynamic construct, such as that provided by semi-rigid bone screw fixation, will compensate for this  
25 phenomenon.

At present, no plating system is known that allows for the placement of bone screws in either a semi-rigid or a rigid construct with a single plate. While some plates will provide for either one of these screw fixations, no plating  
30 system allows the surgeon to use a single plate and to select which of the two types of fixation is desired for the particular spinal pathology and anatomy.

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## SUMMARY OF THE INVENTION

In order to address the needs left unfulfilled by prior systems, the present invention contemplates a novel system for anterior fixation of the spine utilizing an elongated  
5 fixation plate. In one aspect of the invention, the fixation plate is provided with a plurality of holes through which bone screws extend for engagement into a number of vertebrae. In the preferred embodiment, the screw holes include a spherical portion to receive a complementary  
10 formed spherical head of the bone screw. The screw holes further include a cylindrical portion integral with the cylindrical portion and opening to the bottom of the plate.

The flexibility of the present invention anterior fixation plating system is accomplished by the provision of  
15 a fixed angle and a variable angle screw that can be supported within the same screw hole in the plate. Each of the screws includes a threaded shank for screwing into a vertebra and a spherical head to seat within the spherical recess. Both screws include an intermediate portion between  
20 the spherical head and the threaded shank that is configured to reside within the cylindrical portion of the screw hole when the screw is fixed to the plate. The intermediate portion of the fixed angle screw preferably is cylindrical and has an outer diameter sized for a close fit within the  
25 cylindrical portion of the screw hole. In this manner, the fixed angle screw is prevented from rotating or pivoting within the screw hole.

The variable angle bone screw includes an intermediate portion that is also preferably cylindrical. However, the  
30 cylindrical intermediate portion of the variable angle screw has an outer diameter that is significantly smaller than the diameter of the cylindrical portion of the screw hole. This relative difference in diameters between the screw intermediate portion and the screw hole allows the screw to

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assume a range of angles relative to the bottom surface of the plate, even when the screw is locked in position in the plate.

5 In a further aspect of the invention, a locking assembly is provided for locking the bone screws in the plate, thereby preventing screw back-out. In one embodiment of the invention, the locking assembly includes a washer that resides within a recess in the plate. The recess overlaps at least one screw hole in the plate so that the washer can  
10 be seated above the head of the bone screw to hold the screw in place. The locking assembly further includes a threaded set screw that is engaged within a tapped bore concentrically situated within the washer recess. The locking washer is itself configured with a recess so that  
15 the head of the locking screw can reside essentially flush within the locking washer.

In a further embodiment, the locking assembly includes a locking washer having cut-outs formed in its outer surface facing the bone screw head. The cut-outs preferably  
20 correspond to the shape of the screw hole so that the washer does not overlap the screw hole in the region of the cut-out. The washer is held to the plate by a set screw to permit rotation of the washer from a first position in which the cut-outs are aligned with the screw holes, to a second  
25 position in which the outer surface of the washer overlaps the screw holes to lock the screw heads in position. In a further aspect, the washer includes a number of keys projecting from its underside that are configured to mate within corresponding notches formed in the locking washer  
30 recess. The notch and key configuration essentially locks the washer in its position overlapping the screw holes.

The fixation plate assembly of the present invention further contemplates various screw hole arrangements that permit clamping of multiple screws by a single locking  
35 assembly. Other hole arrangements are provided that offer



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several screw fixation options to the surgeon when instrumenting one or more vertebrae. For instance, a four hole arrangement is set forth in which four screw holes are spaced at 90° intervals around a single locking washer and screw assembly. The surgeon can insert either fixed or variable angle screws into any one or more of the four screw holes depending upon the vertebral anatomy.

It is one object of the invention to provide a fixation plate assembly that accommodates either fixed or variable angle screw fixation in a single plate. Another object resides in the provision of a locking assembly that can lock one or more bone screws within the plate.

One benefit achieved by the present invention is that the fixation plate and locking assembly maintain a low profile within the spine. A further benefit is accomplished by the ability to select either a fixed angle or a variable angle screw at any instrumented level and within a single fixation plate.

Other objects and benefits of the invention will become apparent upon consideration of the following written description of the invention, together with the accompanying figures.

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## DESCRIPTION OF THE FIGURES

FIG. 1 is a top perspective view of an anterior plating system according to one embodiment of the present invention.

FIG. 2 is a side elevational view of the plating system  
5 shown in FIG. 1.

FIGS. 3(a)-3(g) are top elevational views of a fixation plate in accordance with the present invention provided in different sizes and configuration.

FIG. 4 is a side elevational view of a fixed-angle bone  
10 screw according to one aspect of the present invention.

FIG. 5 is a side elevational view of a variable angle bone screw in accordance with another aspect of the present invention.

FIG. 6 is a top elevational view of one embodiment of an  
15 elongated plate for use with the anterior plating system according to the present invention.

FIG. 7 is a side cross-sectional view of the plate shown in FIG. 6 taken along line 7-7 as viewed in the direction of the arrows.

FIG. 8 is an end elevational view of the plate shown in  
20 FIG. 6.

FIG. 9 is an end cross-sectional view of the plate shown in FIG. 6 taken along line 9-9 as viewed in the direction of the arrows.

FIG. 10 is a partial side view of a portion of the plate  
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shown in FIG. 6, particularly illustrating the four-hole pattern for the bone screw holes.

FIG. 11 is a partial side view of an end of the plate in FIG. 6, particularly showing the end hole pattern of bone screw holes.

FIG. 12 is a transverse cross-sectional view of the end hole pattern of the plate in FIG. 6, particularly taken along line 12-12 in FIG. 11 as viewed in the direction of the arrows.

FIG. 13 is an end transverse cross-sectional view of the end of the plate shown in FIG. 6, particularly taken along line 13-13 in FIG. 11 as viewed in the direction of the arrows.

FIG. 14 is a cross-sectional view of one bone screw opening in the end hole pattern of the plate shown in FIG. 6, particularly taken along line 14-14 in FIG. 8 as viewed in the direction of the arrows.

FIG. 15 is an enlarged side elevational view of a locking screw according to one aspect of the present invention.

FIG. 16 is an enlarged side elevational view of a locking washer in accordance with a further aspect of the present invention.

FIG. 17 is a partial cross-sectional view of an end hole pattern of the plate shown in FIG. 6, with the screw and washer of FIGS. 15 and 16, respectively shown in their operative position.

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FIG. 18 is a partial cross-sectional view of a plate according to the present invention with the fixed angle bone screws disposed within bone holes in a plate and engaged within a vertebra.

5        FIG. 19 is an enlarged end cross-sectional view of the plate according to the present invention with variable angle screws disposed in the plate and engaged in a vertebra.

10       FIG. 20 is an exploded view of an alternative embodiment of a locking screw assembly for use with an anterior plating system according to a further embodiment of the invention.

FIG. 21 is a top perspective view of the components shown in FIG. 20 in the assembled condition with the locking washer shown in its first position.

15       FIG. 22 is a top perspective view of the locking screw as depicted in FIG. 20, with the locking washer in its second position.

FIG. 23 is a side elevational view of one embodiment of the locking washer used in the assembly of FIGS. 20-22.

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## DESCRIPTION OF THE PREFERRED EMBODIMENTS

For the purposes of promoting an understanding of the principles of the invention, reference will now be made to the embodiment illustrated in the drawings and specific language will be used to describe the same. It will nevertheless be understood that no limitation of the scope of the invention is thereby intended. Any alterations and further modifications in the described device, and any further applications of the principles of the invention as described herein are contemplated as would normally occur to one skilled in the art to which the invention relates.

An anterior plating system or fixation assembly 30 is depicted in FIGS. 1 and 2. In accordance with the present invention, the plating system includes an elongated plate 31 and a number of bone screws 32. The bone screws are held to the plate 31 by way of a plurality of locking assemblies 33. The elongated plate 31 is provided with a plurality of screw holes 34 in a variety of arrangements. The plate also can be divided into vertebral level nodes 35 so that the sides of the plate give a serpentine appearance. In particular, the plate 31 includes recesses between each of the nodes 35 to reduce the outer contour and size of the plate. In addition, the reduced width portion between each of the nodes 35 provides an area of reduced material for additional bending of the plate as may be required by the spinal anatomy.

The plate 31 preferably includes a rounded upper edge 36 that would be in contact with the soft tissue surrounding the spine. The rounded edge 36 reduces the amount of trauma that would be experienced by the surrounding soft tissue. The bottom surface 37 of the plate 31 is preferably configured to contact and engage the vertebral bodies at each of the instrumented levels of the spine. In some embodiments, the bottom surface can be textured to enhance

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its grip on the vertebral body.

Referring now to FIGS. 3(a)-3(g), several variations of the elongated plate 31 are depicted. It is understood that the anterior plating system according to the present  
5 invention can be readily adapted to fix several vertebrae, of course depending upon the length of the plate and the number and arrangement of screw holes 34. The plate depicted in FIGS. 1, 2 and 3(a) includes five vertebral  
10 level nodes 35a so that the plate can be engaged to five vertebrae of the spine. For example, the plate 31a of FIG. 3(a) could be used to fix the vertebrae C1-C5. The elongated plates 31b depicted in FIG. 3(b) is sized and configured to span three or four vertebrae, depending upon the instrumented vertebral levels. In this instance, the  
15 plate 31b includes four vertebral level nodes 35b, with two nodes at the opposite ends of the plate and two nodes offset from each other in the middle portion of the plate.

A modification of the plate 31b is depicted in FIG. 3(c). In this case, the plate 31c includes three nodes 35c,  
20 with the nodes on the opposite side of the middle portion of the plate being directly aligned at the same vertebral level. The plates of FIGS. 3(d)-3(e), namely plates 31d and 31e, are similar to the plate 31c although their lengths are progressively shorter. The last two plates 31f and 31g, in  
25 FIGS. 3(f)-3(g), respectively, provide for instrumentation of two vertebral levels, each having two nodes 35f and 35g, respectively.

In accordance with the present invention, the elongated plates 31a-31g provide a variety of hole patterns at each of  
30 the vertebral level nodes 35a-35g. These hole patterns provide, at a minimum, for at least two bone screws to be engaged into each respective vertebra. As discussed above, it has been found that the placement of two or more screws in each vertebral body improves the stability of the  
35 construct. It is one object of the present invention not

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only to provide for multiple screw placement in each vertebral body, but also to provide means for locking the screws to the elongated plate to prevent backout or loosening of the bone screws. Consequently, in a further aspect of the invention, various hole patterns are provided that address these objects. One pattern is an end hole pattern 38, as shown at the ends of plate 31 in FIG. 1 and plate 31a in FIG. 3(a). In this arrangement, two screw holes 34 are laterally disposed at a single node 35a. A single locking assembly is disposed between the two screw holes 34 and is configured to lock bone screws disposed within each respective hole. A similar arrangement is provided by the middle hole pattern 39 in which two screw holes are situated at a single vertebral level. A locking assembly is disposed between the two bone screw holes and is configured to lock bone screws within the respective holes in the same manner as screws are locked in the end hole pattern 38.

The present invention contemplates a plate carrying four-hole patterns. The four-hole pattern 40 illustrated in FIG. 1 and FIGS. 3(a) and 3(b), provides four bone screw holes 34 in a diamond pattern. A single locking assembly 33 is centrally disposed between all of the bone screw holes so that bone screws within the respective holes are simultaneously locked by the single locking assembly. In the five node plate 31a of FIG. 3(a), two such four-hole patterns 40 are provided. In the three-node plate 31d of FIG. 3(d), only a single four-hole pattern 40 is required. It can be appreciated that the four-hole pattern 40 provides a great degree of flexibility to the surgeon in determining how many bone screws 32 will be engaged into a single vertebra, and in what arrangement. For example, as shown in FIG. 1, two screws are situated in the laterally opposite screw holes at the vertebral level node 35. Alternatively, bone screws could be placed in the longitudinally opposite

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screw holes oriented along the length of the plate 31a. Less conventional arrangements contemplate bone screws being placed in immediately adjacent screw holes 34, or placing three bone screws in three of the holes of the four-hole pattern 40. Again, the selection of bone screws and their arrangement can be left to the surgeon and will be based upon the type of correction or fixation required and the anatomy of the particular instrumented vertebra.

5 A further arrangement for screw holes 34 is provided by the four-hole cluster 41 depicted in FIGS. 3(b) and 3(c). In the four-hole cluster 41 in plate 31b, two hole pairs 41a and 41b are provided. Each of the hole pairs includes its own locking assembly to lock the two screws into the screw bores of the respective hole pairs. As shown in FIG. 3(b), 15 the orientation of the particular hole pairs provides one screw hole from each pair generally laterally relative to each other in a single vertebra. The other of the bone screw holes in each respective pair is longitudinally offset from the central screw holes, being disposed closer to the ends of the plate 31b. In this manner, the two central 20 holes of each of the two holes pairs can be engaged in a single vertebra, while the remaining screw holes of the hole pairs 41a and 41b can be disposed in the superior and inferior adjacent vertebrae. Most preferably, however, each of the screw holes in the four-hole cluster 41 is generally 25 oriented over or slightly offset from a single vertebra. The surgeon then has the option to selected any of the screw holes in the two hole pairs 41a or 41b that is optimally aligned over the vertebra.

30 A similar arrangement is found in the plate 31C which includes a four-hole cluster 42. In this case, it can be seen that the four-hole cluster 42 includes two hole pairs 42a and 42b, in a manner similar to the four-hole cluster 41 of FIG. 3(b); however in this case, the hole pairs are 35 arranged closer to each other, principally because the plate



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31c is shorter than the plate 31b. In both of the four-hole clusters 40 and 41, the locking assemblies are provided to lock only a pair of bone screw holes rather than all four holes with a single locking assembly.

5       The invention further contemplates a three-hole pattern, such as pattern 43 provided in the plate 31f in FIG. 3(f). In this pattern 43, a single locking assembly is used to fix three bone screws within the respective screw holes. A  
10       five-hole pattern 44 is provided on plate 31g, as shown in FIG. 3(g). In this five-hole pattern, a single hole is arranged centrally between four outlying holes. Two locking  
15       assemblies 33 are provided to lock a pair of the outlying four screw holes together with the central hole. In this configuration, the central hole is held in place by two  
locking assemblies, while each of the outlying four holes is held in place by a single locking assembly.

      In one important aspect of the present invention, the bone screw 32 can either constitute a fixed angle screw 50, as shown in FIG. 4, or a variable angle screw 60, as shown  
20       in FIG 5. Turning first to FIG. 4, the fixed angle screw 50 includes a threaded shank 51. The threaded shank is preferably configured to engage the cancellous bone of a vertebral body. The threaded shank can also include self  
tapping threads, although the specific illustrated  
25       embodiment requires prior drilling and tapping of the vertebral body for insertion of the fixed angle screw 50. The screw 50 includes an intermediate portion 52 that is disposed between the threaded shank 51 and the head 54 of the screw. The threaded shank 51 extends into the  
30       intermediate portion 52 by a thread run-out 53, according to standard thread machining practices. As can be seen from FIG. 4, the intermediate portion 52 includes a short segment that does not bear any threads. This short segment has an outer diameter  $D_1$  that will assume significance during  
35       consideration of the details of the elongated plate 31

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discussed herein.

The head 54 of the fixed angle screw 50 includes a tool recess 55 that is configured to receive a driving tool. In one specific embodiment, the tool recess 55 can be a hex recess, or in an alternative embodiment, a TORX\* type recess. The head 54 includes a truncated or flattened top surface 56 and a spherical surface 57 between the top surface 56 and the intermediate portion 52. The head 54 includes a height  $H_1$  between the top surface 56 and the intermediate portion 52.

In one specific embodiment, the intermediate portion 52, and more specifically the segment between the thread run-out 53 and the head 54, has a height of 1.2mm and a diameter of 4.05mm. The height  $H_1$  of the head 54 in this specific embodiment has a dimension of 2.6mm. In this specific embodiment, the dimensions of the head 54 and intermediate portion 52 are calibrated for length of the threaded shank 51 of between 10mm and 20mm. In this specific embodiment, the bone screws are preferably configured for engagement in the cervical spine. In another aspect of the specific embodiment, the root diameter of the threaded shank 51 is tapered over the first four convolutions to the final root diameter, which is about 2.43mm in the specific embodiment.

Turning to FIG. 5, the details of the variable angle screw 60 can be seen. Like the fixed angle screw 50, the variable angle screw 60 includes a threaded shank 61 and an intermediate portion 62. However, in contrast to the fixed angle screw 50, the intermediate portion 62 has an outer diameter  $D_2$  that is approximately equal to the root diameter of the threaded shank 61. In other words, the diameter  $D_2$  of the intermediate portion 62 of the variable angle screw 60 is less than the diameter  $D_1$  of the intermediate portion 52 of the fixed angle screw 50. Like the fixed angle screw 50, the threads of the shank 61 run out into the intermediate portion 62, leaving the portion 62

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with a threaded height of about 0.8mm.

The variable angle screw 60 also includes a head 64 having a tool recess 65 defined from the truncated top surface 66. The head 64 also includes a spherical surface 67 disposed between the top surface 66 and the intermediate portion 62. The head 64 of the variable angle screw 60 has a height  $H_2$  between the top surface and the intermediate portion that is greater than the height  $H_1$  of the head 54 of the fixed angle screw 50.

In the specific embodiment of the variable angle screw 60, the head 64 has a height  $H_2$  of about 3.3mm. This greater height is attributable to the smaller diameter  $D_2$  of the intermediate portion 64 relative to the diameter  $D_1$  of the intermediate portion 52 of the fixed angle screw 50. Both the head 54 and the head 64 of the respective screws have a comparable outer diameter, which is 4.88mm in the specific embodiment. In the case of the variable angle screw, the diameter of the spherical surface 67 continues around a greater arc because the intermediate portion 62 has a smaller diameter. In one specific embodiment, the intermediate portion 62 has a diameter  $D_2$  of 2.9mm, compared to the 4.05mm diameter  $D_1$  for the fixed angle screw 50.

Like the fixed angle screw 50, the variable angle screw 60 can be preferably provided in lengths between 10mm and 20mm, for use at different locations in the spine.

The engagement of the bone screws 50 and 60 to the elongated plate 31 require further discussion of the details of the plate itself. These details can be discerned with reference to FIGS. 6-14. In FIG. 6, the longer plate 31a is depicted, although it is understood that the various geometric structural aspects of this plate are repeated among each of the plates 31b-31g. As discussed previously, the plate 31a includes undulating edges, with the peaks of the undulation corresponding to the vertebral level nodes

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35. The plate material between the nodes is reduced to minimize the bulk of the plate and to provide a thinner plate width in areas that may require additional bending for implantation. In the specific embodiment, a plurality of screw holes 34 is provided throughout the length of the plate and in various patterns. In the illustrated embodiment of FIG. 6, the holes are oriented in end hole patterns 38 at opposite ends of the plate, middle hole pattern 39 centrally located in the plate, and two four-hole patterns 40 disposed between the end hole patterns 38 and the middle hole pattern 39. In each case, the hole patterns require a locking screw assembly 33. Consequently, the plate 31a, along with all the other plate design contemplated by the present invention, includes tapped bore 70 situated within a concentric locking recess 71. (See FIG. 7). As shown in FIGS. 6 and 7, the locking recess 71 intersects or overlaps adjacent bone screw holes 34. In the case of the end hole pattern 38, the locking recess 71 overlaps the two screw holes, while in the case of the four-hole pattern 40, the locking recess 71 overlaps the four holes 34 arranged in a diamond pattern.

To accommodate the anterior application of this fixation plate assembly 30, the plate is curved in two degrees of freedom. Specifically, the bottom surface 37 of the plate can be curved along a large radius R, as shown in FIG. 7, to accommodate the kyphotic curvature of the cervical spine. In addition, the bottom surface 37 forms a medial/lateral curvature L, as shown in FIG. 9, to correspond to the curvature of the vertebral body. It is understood that the plate 31a can be bent along its longitudinal length between the vertebral level nodes 35, as required to accommodate the particular spinal anatomy and vertebral pathology.

The screw holes 34 in the plate 31a are defined by a spherical recess 75 (see FIGS. 7 and 9) having a diameter measured about an axis 75a intersecting the elongated plate

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31a. (See FIGS. 11 and 12). In a further aspect of the invention, the screw holes 34 include a cylindrical bore 77 communicating between the spherical recess 75 and the bottom surface 37 of the plate 31. The cylindrical bore 77 defines a diameter along the axis 75a. To facilitate insertion of drill guides, drills and the bone screws 32, each screw hole 34 includes a flared recess 79. The flared recess is preferably formed as a tapered counter-sink along an axis 79a (see FIGS. 11 and 13). This flared recess 79 overlaps the locking recess 71 of the locking assembly 33 at a recess overlap 80, shown best in FIGS. 7, 9 and 13.

In one specific embodiment, the spherical recess 75 is defined at a diameter of 5.0mm, which is slightly larger than the diameter of the heads 54, 64 of the bone screws 50, 60. The cylindrical portion of the screw holes 34 is defined at a diameter of 4.1mm, in the specific embodiment, which is again slightly larger than the diameter  $D_1$  of the intermediate portion 52 of the fixed angle screw 50. It should be understood, of course, that the diameter of the cylindrical bore 77 is significantly larger than the diameter  $D_2$  of the intermediate portion 62 of the variable angle screw 60.

Again in the specific embodiment, the axis 75a of both the spherical recess 25 and the cylindrical bore 77 is oriented generally normal to the bottom surface 37 of the plate 31a, when viewed in the direction of the longitudinal axis of the plate. In other words, the axis 75 is normal to the plate in the direction of the medial/lateral curvature L of the plate. On the other hand, the orientation of the screw holes 34 can vary between the vertebral level nodes 35, and most particularly when considering the end hole patterns 38. In this specific embodiment, the flared recess 79, and specifically its axis 79a, can be colinear with the axis 75a of the recess 75, for the hole patterns in the interior of the elongated plate 31a. For example, as shown

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in FIG. 6, the flared recess 79 can be approximately concentric with the screw holes 34 for the middle hole pattern 39. On the other hand, the flared recess 79, and specifically the axis 79a, at the end hole patterns 38, are offset at an angle A, as depicted in FIG. 14. In particular, the axis 75a of the spherical recess is offset at an angle A of about 12 degrees relative to a perpendicular from the bottom surface 37 of the plate 31a. In this manner, the bone screws will be directed outwardly toward the end of the plate upon insertion into the screw holes 34.

The details of the locking assembly 33 can be gleaned from consideration of FIGS. 15-17. In this specific embodiment, the locking assembly 33 includes a locking screw 85 having machine threads 86. In one specific embodiment, the locking screw 85 terminates in a sharp point 86a to permit penetration of the vertebral body. The head 87 of the locking screw 85 includes a lower conical surface 88 and a tool recess 89 defined therein for receiving a driving tool.

The locking assembly 33 also includes a washer 90 having an outer surface 91. In the specific preferred embodiment, the outer surface 91 is defined by a curved convex surface 92. The washer 90 also includes a screw bore 93 extending therethrough in communication with a tapered bore 94. The tapered bore 94 has a complementary mating configuration relative to the conical surface 88 of the head 87 of locking screw 85. The mating conical features between the locking screw and washer provides a self-centering capability for the washer as the locking screw is tightened onto the plate. The screw bore 93 is sized to receive the machine threads 86 therethrough for engagement with the tapped bore 70 of the plate 31a, as shown in FIG. 17. As illustrated in FIG. 17, the outer surface 91 of the washer 90 intersects the recess overlap 80 between the flared recess 79 and the

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respective spherical recess 75 of the adjacent screw holes 34. In a specific embodiment, the locking recess 71 has a diameter of 6mm to accept the washer 90 having an outer diameter of 5.3mm. Again in this specific embodiment, the  
5 curved convex surface 92 of the washer 90 is curved at a radius of about 2.5mm so that the lowermost portion of the washer has a smaller diameter of about 4.3mm.

Referring now to FIGS. 18 and 19, the use of the fixation plate assembly 30 is illustrated. In FIG. 18, a  
10 pair of fixed angle screws 50 are disposed within respective bores 34 so that the threaded shanks 51 project beyond the lower surface 37 of the plate 31 and into the vertebral body V. The intermediate portion 52 of the fixed angle screw 50 extends through the cylindrical bore 77 of the screw holes  
15 34. The spherical surface 57 of the head 54 of the screw contacts the spherical recess 75 of the screw hole 34 as the fixed angle screw 50 is threaded into the vertebral body V. Once the screw 50 is completely seated within the spherical recess 75, the intermediate portion 52 provides a snug  
20 relationship relative to the cylindrical bore 77 so that the fixed angle screw 50 is not able to pivot or translate relative to the plate 31.

In order to ensure secure fixation of the screw 50 within plate 31, the locking assembly 33 is tightened onto  
25 the heads 54 of the two bone screws 50. In particular, the locking screw 85 is threaded into the tapped bore 70 to draw the washer 90 into contact with the screw heads. The convex surface 92 seats against the spherical surface 57 of the bone screw heads 54 to firmly seat the screw heads within  
30 the plate spherical recess 75. Preferably, the locking washer 90 will advance sufficiently far into the locking recess 71 to rest substantially flush with the top surfaces 56 of the bone screws 50. In the locked position, the washer 90 does not bottom out within the locking recess 71.

35 In a further aspect of the invention, the locking

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assembly 33 is loosely fixed on the plate 31 so that the surgeon need not fiddle with the locking assembly when the plate is engaged to a vertebra. In particular, the locking screw 85 is pre-threaded through the locking washer 90 and into the tapped bore 70 until about three or fewer threads of the locking screw project below the bottom surface 37 of the plate. The locking screw 85 is then staked at the thread nearest the plate so that the screw cannot be removed or backed out through the tapped bore 70. Of course, the locking screw 85 can be advanced further through the bore 70- when it is necessary to enable the locking assembly 33. As previously mentioned, the sharp point 86a of the locking screw 85 is preferably configured to penetrate the cortical bone. With the locking screw staked to the plate, the sharp point 86a will penetrate the vertebra V when the plate 31 is initially positioned on the bone. In this instance, the locking screw 85 helps locate and temporarily stabilize the plate on the vertebra V as the bone screws 50 are implanted into the bone. This temporary location feature provided by the locking screw 85 can also be used when a drill guide is used to drill and tap the vertebra to receive the bone screws 50.

The locking assembly 33 is configured so that the washer 90 can be moved clear of the screw holes 34 when the locking screw 85 is staked to the plate 31. Thus, even with the locking assembly 33 in its loosened position, the bone screws 50, 60 can still be inserted into the screw holes 34, preferably by pulling the washer 90 away from the plate 31.

The use of the variable angle bone screw 60 is depicted in FIG. 19. The locking assembly 33 functions as described above to lock the heads 64 of the variable angle screws 60 within the plate 31. Specifically, the convex surface 92 of the washer 90 contacts and applies pressure to the spherical surfaces 67 of the respective bone screws 60. However, with the variable angle screws 60, the intermediate portion 62



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does not fit snugly within the cylindrical bore 77 of the screw holes 34. Thus, even with the head 64 of each screw 60 residing solidly within the spherical recess 75, the bone screw 60 can still be angulated relative to the plate and to the axis of the spherical recess 75 and cylindrical bore 77. It is understood that the degree of angulation is restricted by the difference in diameters between the cylindrical bore 77 and the intermediate portion 62 of the variable angle screw 60. In one preferred embodiment, the relative diameters permit angulation of up to 20° from the axis 75a of the recess 75 and bore 77.

During implantation, the variable angle capability of the screw 60 allows the surgeon to place the bone screw within the vertebra at any angle within the defined angulation limits (20° in one specific embodiment). Thus, the variable angle screw 60 provides greater flexibility than does the fixed angle screw 50 for orienting the bone screw relative to the anatomy of the vertebra. Moreover, this variable angle capability allows a limited degree of micro-motion between the screw and the plate when the fixation assembly 30 is implanted within a patient. In other words, as the spine is loaded and as load is transmitted through the screws and plate, the plate and vertebra may translate relative to each other. The variable angle screw 60 accommodates this relative movement by pivoting within the spherical recess 75. On the other hand, the fixed angle screw 50 prevents this relative movement. The choice between using a fixed or a variable angle screw can be left to the surgeon depending upon the pathology being treated. The fixation plate assembly 30 according to the present invention allows this choice to be made at any point during the surgical procedure.

A further embodiment of the present invention is depicted in FIGS. 20-23. In this embodiment, an alternative locking mechanism is provided. A plate assembly 100

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includes an elongated plate 101 receiving bone screws 102. A locking assembly 103 is provided to lock the bone screw within the plate. The plate 101 defines a spherical recess 105 to receive the spherical head 115 of the bone screw.

5 The threaded shank 114 of the bone screw projects through the recess. It is understood that the bone screw 102 and spherical recess 105 can be similar to the like components described above.

In accordance with this embodiment, the plate further

10 includes a tapped bore and concentric locking recess 107 disposed adjacent the spherical recess 105 for the bone screw. The spherical and locking recess contact at a locking overlap 108. A notch 110 extends transversely across the locking recess 107 in this embodiment.

15 The locking assembly 103 includes a locking washer 120 and locking screw 121. Like the prior locking screw, the screw 121 includes machine threads 122 and an enlarged head 123. The head sits within a recess 124 in the washer 120, with the machine threads 122 projecting through a bore 125.

20 The machine threads 122 are configured to engage the tapped bore 106 of the plate 101. The locking screw 121 can be staked onto the plate 101 as discussed with respect to the prior embodiment.

The locking washer 120, while functioning similar to the

25 washer of the prior embodiment, offers a different construction than the previous washer. Like the washer 90, the locking washer 120 includes an outer circumferential surface 127 that is preferably convex to mate with a spherical head of the bone screw 102. However, in one

30 modification, the washer 120 includes cut-outs 128 in the circumferential surface 127. The cut-outs 128 are arranged to coincide with the screw recesses 105 when the locking washer is in a first position, as illustrated in FIG. 21. This structure of the washer 120 allows the washer to remain

35 clear of the recess 105 for unimpeded insertion of the bone

-25-

screw 102.

In certain embodiments, the washer 120 is provided with two such cut-outs at diametrically opposite positions on the washer. Most preferably, the cut-outs 128 are aligned with the relative orientation of screw holes 105 in the plate 101. For example, a washer 120 adapted for a three hole pattern 43, as depicted in FIG. 3(f), would have three cut-outs 128 at 120° intervals. Similarly, a locking washer 120 modified for use with the four hole pattern 40 of FIG. 3(a) would have four cut-outs 128 spaced 90° apart on the circumferential surface 127 of the washer.

Once the bone screws have been implanted through the appropriate screw recesses 105, the locking washer 120 can be rotated into its locking position shown in FIG. 22. In this position, the cut-outs 128 are rotated away from the screw recesses 105 so that the washer, and more particularly the outer circumferential surface 127, overlaps the screw recess 105. In a further modification from the prior washer, the washer 120 includes a number of keys 129 on the underside of the washer. The keys are configured to sit within a corresponding notch 110 in the plate 101 when the locking washer is in the locking position shown in FIG. 22. Once the bone screws have been implanted and the locking washer 120 has been rotated into its locking position, the keys 129 fall into the notches 110 to fix the position of the washer while the locking screw 121 is tightened.

While the invention has been illustrated and described in detail in the drawings and foregoing description, the same is to be considered as illustrative and not restrictive in character, it being understood that only the preferred embodiments have been shown and described and that all changes and modifications that come within the spirit of the invention are desired to be protected.

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What is claimed is:

1. A bone fixation system comprising:

an elongated plate having a top surface and a bottom surface and defining a plurality of holes between said surfaces, at least one of said plurality of holes including a spherical recess portion adjacent said top surface having a first diameter and defining an opening at said bottom surface having a second diameter less than said first diameter;

10 a first bone engaging fastener having a first elongated shank defining bone engaging threads thereon, a first enlarged head and a first intermediate portion between said shank and said head, said first shank having an outer diameter less than said second diameter so said first bone  
15 engaging fastener can be inserted through said at least one hole from said top surface of said plate, said first enlarged head defining a partially spherical surface complementary to said spherical recess of said at least one hole, and said first intermediate portion having a third  
20 diameter that is substantially smaller than said second diameter, whereby said first head of said first bone engaging fastener can be pivoted within said recess portion of said at least one hole so that said first bone engaging fastener can assume a plurality of angles relative to said  
25 bottom surface of said plate; and

a second bone engaging fastener having a second elongated shank defining bone engaging threads thereon, a second enlarged head and a second intermediate portion between said shank and said head, said second shank having  
30 an outer diameter less than said second diameter so said second bone engaging fastener can be inserted through said at least one hole from said top surface of said plate, said second enlarged head defining a partially spherical surface complementary to said spherical recess of said at least one  
35 hole, and said second intermediate portion having a

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substantially cylindrical portion with a fourth diameter that is approximately equal to said second diameter, whereby said second head of said second bone engaging fastener cannot be pivoted within said recess portion of said at least one hole so that said second bone engaging fastener can assume a fixed orientation relative to said bottom surface of said plate.

2. A bone fixation system comprising:

an elongated plate having a top surface and a bottom surface and defining a plurality of holes between said surfaces, at least one of said plurality of holes including a spherical recess portion adjacent said top surface having a first diameter and defining an opening at said bottom surface having a second diameter less than said first diameter;

a bone engaging fastener having a elongated shank defining bone engaging threads thereon, a enlarged head and an intermediate portion between said shank and said head, said shank having an outer diameter less than said second diameter so said bone engaging fastener can be inserted through said at least one hole from said top surface of said plate, said enlarged head defining a partially spherical surface complementary to said spherical recess of said at least one hole; and

a locking screw assembly for locking said head of said bone engaging fastener within said recess portion of said

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plate, including;

a fastener bore defined in said plate adjacent said at least one hole;

5 a washer defining a central aperture and a recess communicating with said aperture, said washer further having an outer circumferential surface configured to contact said head of said bone engaging fastener when said bone engaging fastener is extended through said at least one hole; and

10 a locking fastener having a head configured to be recessed within said recess of said washer and an elongated shank extending through said central aperture and configured to engage said fastener bore of said plate.

15 3. A bone fixation system comprising:

an elongated plate having a top surface and a bottom surface and defining a plurality of holes between said surfaces, at least one of said plurality of holes including a spherical recess portion adjacent said top surface having a first diameter and defining an opening at said bottom surface having a second diameter less than said first diameter;

20 a bone engaging fastener having a elongated shank defining bone engaging threads thereon, a enlarged head and an intermediate portion between said shank and said head, said shank having an outer diameter less than said second diameter so said bone engaging fastener can be inserted through said at least one hole from said top surface of said plate, said enlarged head defining a partially spherical surface complementary to said spherical recess of said at least one hole; and

30 a locking screw assembly for locking said head of said bone engaging fastener within said recess portion of said

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plate, including;

a fastener bore defined in said plate adjacent said at least one hole;

5 a washer defining a central aperture and a recess communicating with said aperture, said washer further having an outer circumferential surface configured to contact said head of said bone engaging fastener when said bone engaging fastener is extended through said at least one hole, said outer circumferential surface  
10 having a concave curvature substantially corresponding to said partially spherical surface of said head of said bone engaging fastener; and

a locking fastener having a head configured to engage said washer and an elongated shank extending  
15 through said central aperture and configured to engage said fastener bore of said plate.

4. A bone fixation system comprising:

an elongated plate having a top surface and a bottom surface and defining a plurality of holes between said  
20 surfaces, at least one of said plurality of holes including a spherical recess portion adjacent said top surface having a first diameter and defining an opening at said bottom surface having a second diameter less than said first diameter;

25 a bone engaging fastener having a elongated shank defining bone engaging threads thereon, a enlarged head and an intermediate portion between said shank and said head, said shank having an outer diameter less than said second diameter so said bone engaging fastener can be inserted  
30 through said at least one hole from said top surface of said plate, said enlarged head defining a partially spherical surface complementary to said spherical recess of said at least one hole; and

a locking screw assembly for locking said head of said

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bone engaging fastener within said recess portion of said plate, including;

a fastener bore defined in said plate adjacent said at least one hole;

5 a washer defining a central aperture and a bottom surface configured to contact said head of said bone engaging fastener when said bone engaging fastener is extended through said at least one hole, said washer further defining a circumferential surface having a  
10 first portion overlapping said at least one hole when said washer is in a first position relative to said at least one hole and having a second portion that does not overlap said at least one hole when said washer is rotated from said first position to a second position,  
15 whereby said bone engaging fastener can be inserted through said at least one hole with said washer engaged to said plate when said washer is in said second position; and

20 a locking fastener having a head configured to be recessed within said recess of said washer and an elongated shank extending through said central aperture and configured to engage said fastener bore of said plate.

5. A bone fixation system comprising:

25 an elongated plate having a top surface and a bottom surface and defining a plurality of holes between said surfaces, at least one of said plurality of holes including a spherical recess portion adjacent said top surface having a first diameter and defining an opening at said bottom  
30 surface having a second diameter less than said first diameter;

a bone engaging fastener having a elongated shank defining bone engaging threads thereon, a enlarged head and an intermediate portion between said shank and said head,



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said shank having an outer diameter less than said second diameter so said bone engaging fastener can be inserted through said at least one hole from said top surface of said plate, said enlarged head defining a partially spherical surface complementary to said spherical recess of said at least one hole; and

a locking screw assembly for locking said head of said bone engaging fastener within said recess portion of said plate, including;

10 a fastener bore defined in said plate adjacent said at least one hole;

a notch defined in said plate adjacent said fastener bore;

15 a washer defining a central aperture and a recess communicating with said aperture, said washer further having an outer surface configured to contact said head of said bone engaging fastener when said bone engaging fastener is extended through said at least one hole, said washer further including a key adjacent said 20 central aperture configured to seat within said notch in said plate to prevent rotation of said washer relative to said plate; and

25 a locking fastener having a head configured to be recessed within said recess of said washer and an elongated shank extending through said central aperture and configured to engage said fastener bore of said plate.

6. A bone fixation system comprising:  
four bone engaging fasteners, each having an enlarged head and a threaded shank;

30 an elongated plate sized to span between at least three vertebrae, said plate defining two sets of two holes, each configured to receive said threaded shank of said bone engaging fasteners therethrough, a first set having a first

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hole aligned over a first vertebra and a second hole aligned over a second vertebra when said plate spans the vertebrae, and a second set having a third hole adjacent said second hole and aligned over the second vertebra, and a fourth hole  
5 aligned over a third vertebra adjacent the second vertebra; and

a pair of locking screw assemblies, one each for each of said two sets of two holes, each of said locking screw assemblies having a washer configured to overlap each of  
10 said two holes of said first and second sets when a bone engaging fastener extends through a corresponding one of said holes.

7. A bone fixation system comprising:

four bone engaging fasteners, each having an enlarged  
15 head and a threaded shank;

an elongated plate sized to span between at least three vertebrae, said plate defining a sets of four adjacent holes, each configured to receive said threaded shank of said bone engaging fasteners therethrough; and

20 a locking screw assembly having a washer configured to overlap each of said four holes when a bone engaging fastener is extended through a corresponding one of said four holes.

8. A bone fixation system comprising:

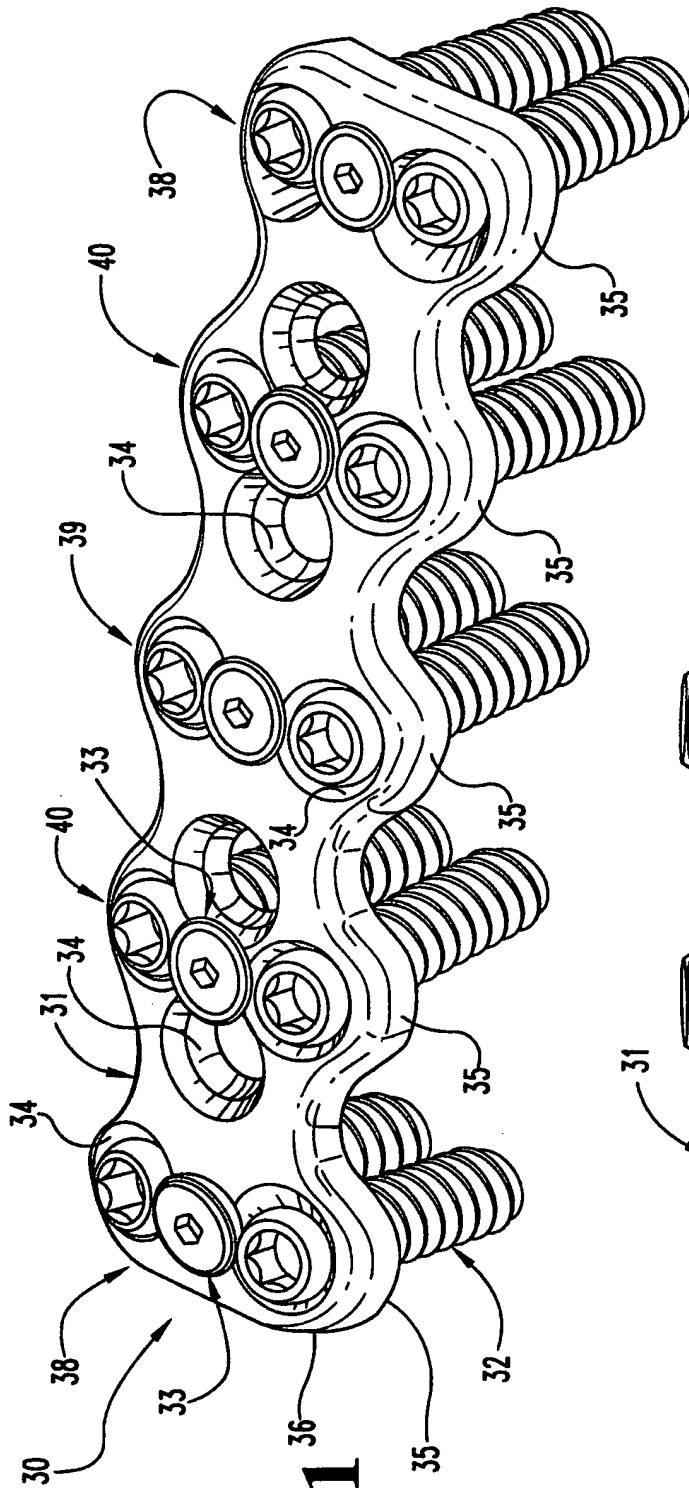
25 five bone engaging fasteners, each having an enlarged head and a threaded shank;

an elongated plate sized to span between at least three vertebrae, said plate defining three sets of two holes, each configured to receive said threaded shank of said bone  
30 engaging fasteners therethrough, a first set having two holes aligned over a first vertebra, a second set having one hole aligned over a second vertebra when said plate spans the three vertebrae, and a third set having two holes

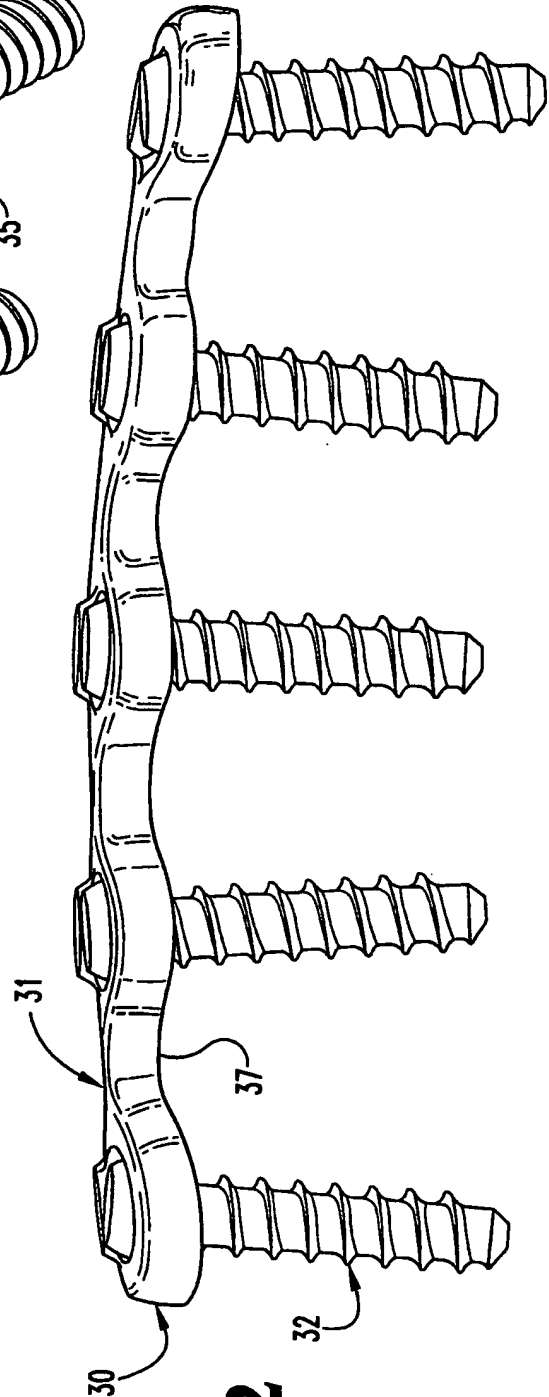
-33-

aligned over the third vertebra; and

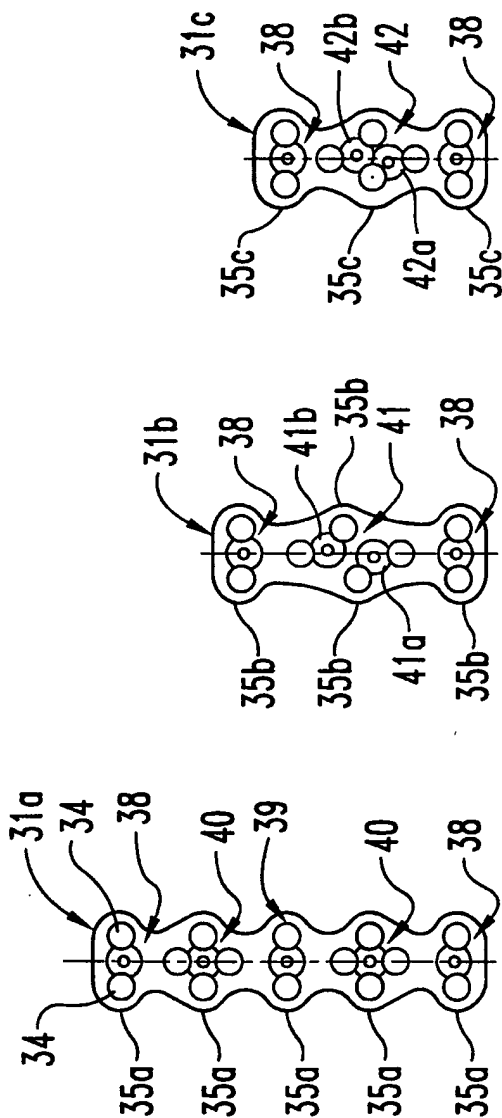
5 a pair of locking screw assemblies, a first one of said locking screw assemblies disposed between said first set and said second set of holes and including a first washer  
10 configured to overlap each of said two holes of said first set and said one hole of said second set when a bone engaging fastener extends through a corresponding one of said holes, and a second one of said locking screw assemblies disposed between said second set and said third set of holes and including a second washer configured to overlap said one hole of said second set and each of said two holes of said third set when a bone engaging fastener extends through a corresponding one of said holes.



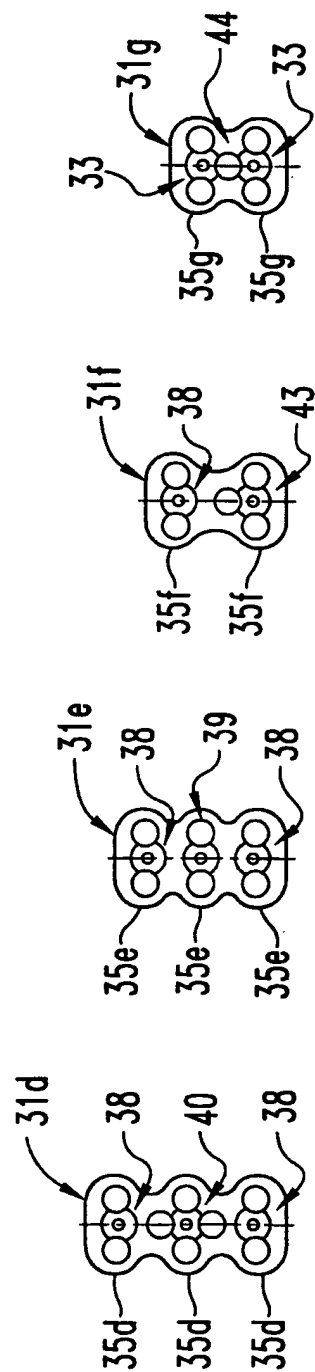
**Fig. 1**



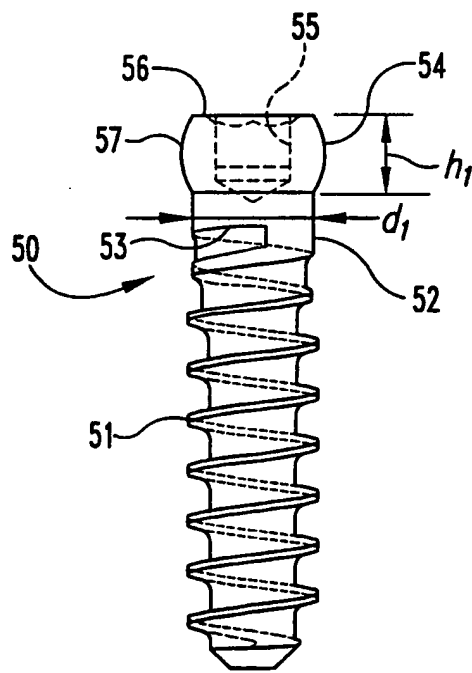
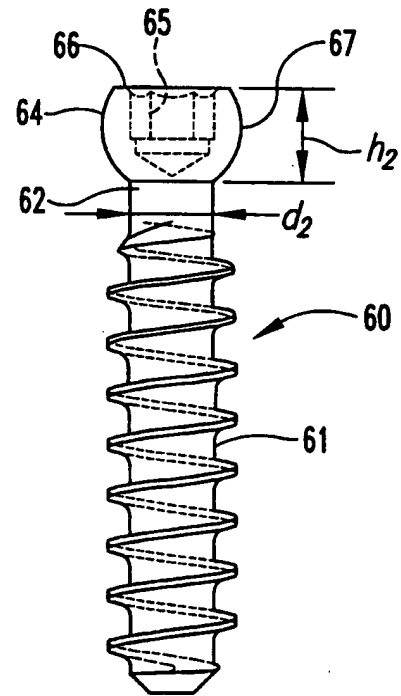
**Fig. 2**



**Fig. 3a** **Fig. 3b** **Fig. 3c**



**Fig. 3d** **Fig. 3e** **Fig. 3f** **Fig. 3g**

**Fig. 4****Fig. 5**

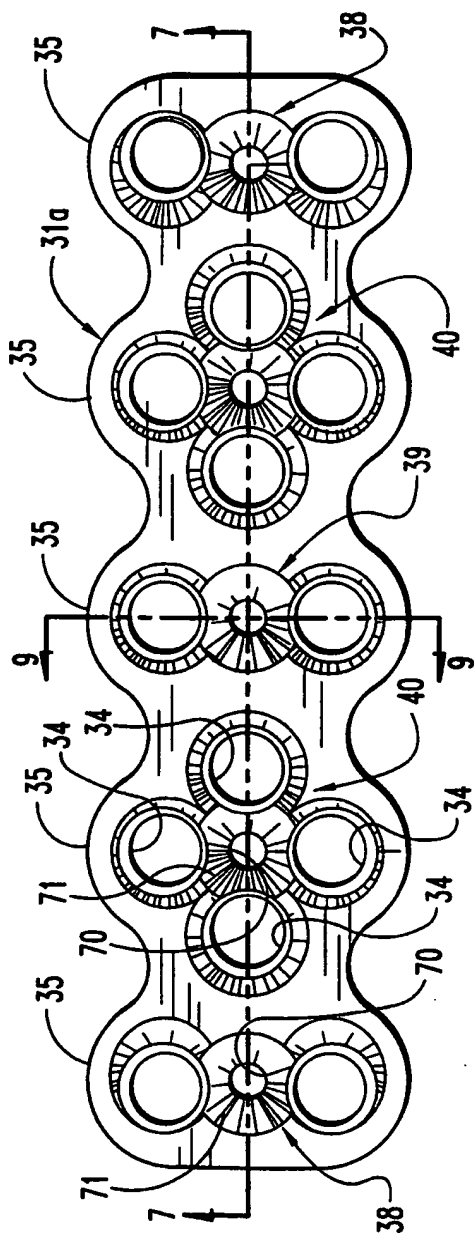


Fig. 6

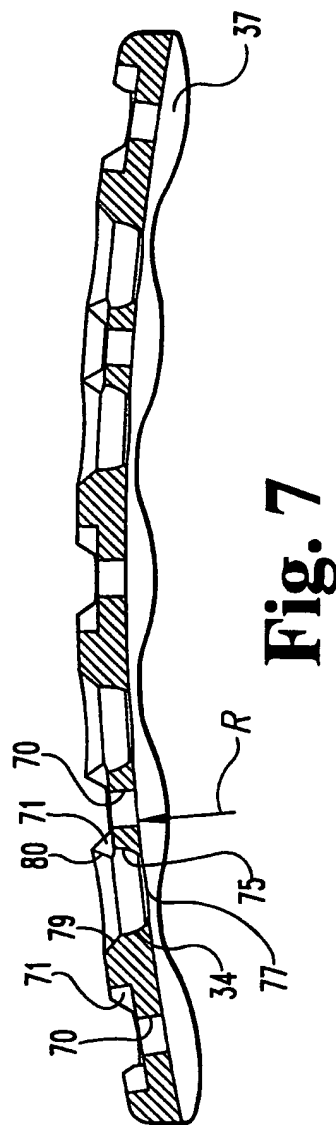


Fig. 7

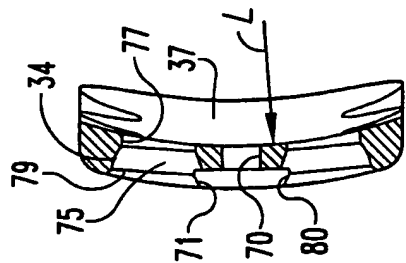


Fig. 9

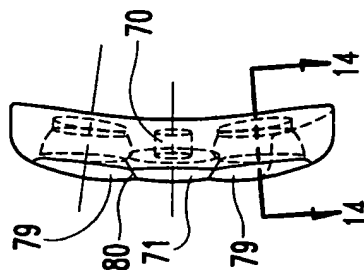
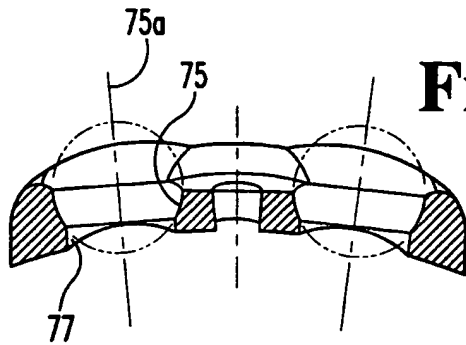
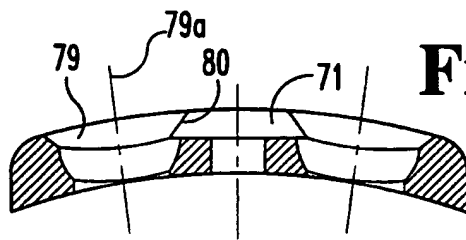


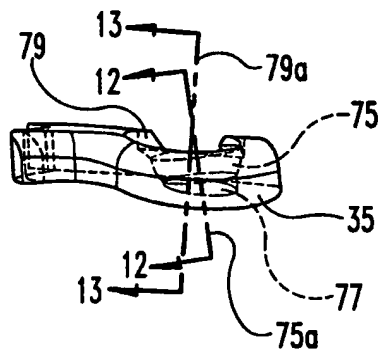
Fig. 8



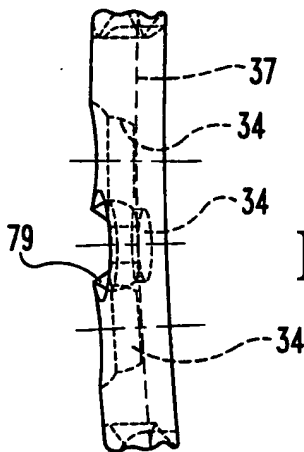
**Fig. 12**



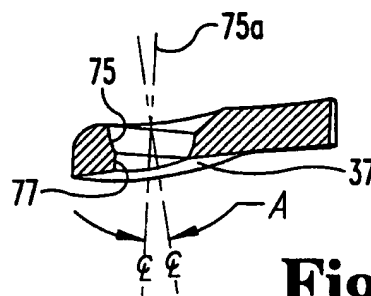
**Fig. 13**



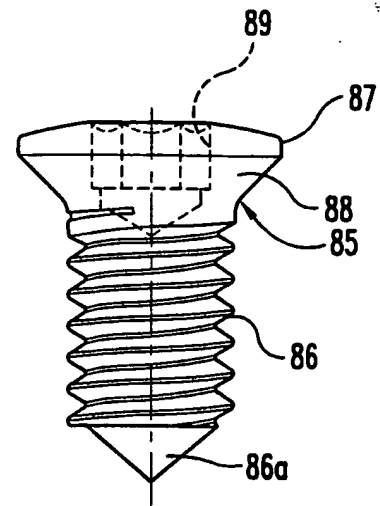
**Fig. 11**



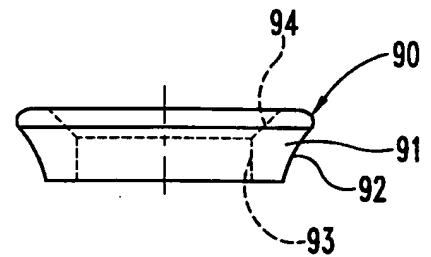
**Fig. 10**



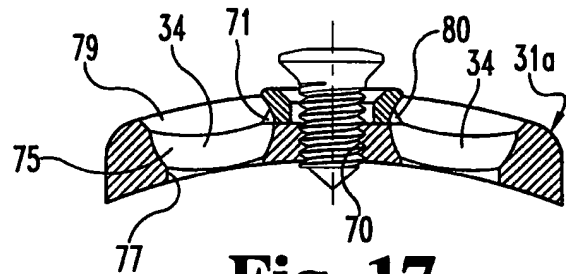
**Fig. 14**



**Fig. 15**



**Fig. 16**



**Fig. 17**



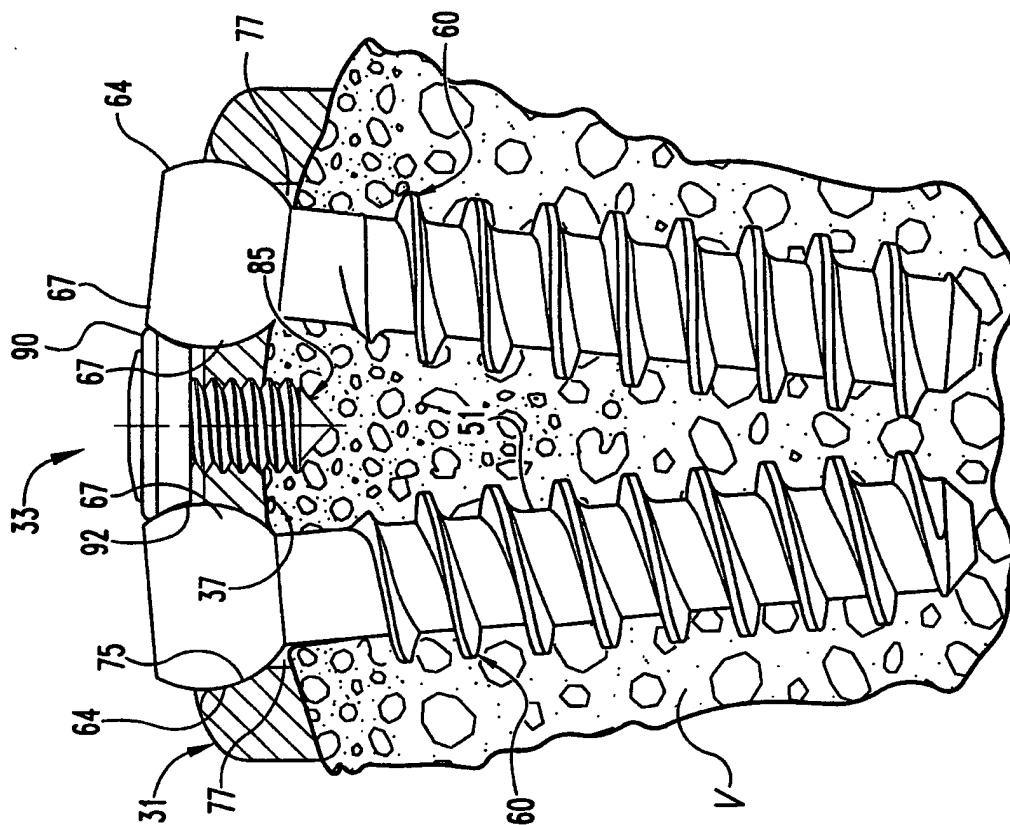


Fig. 19

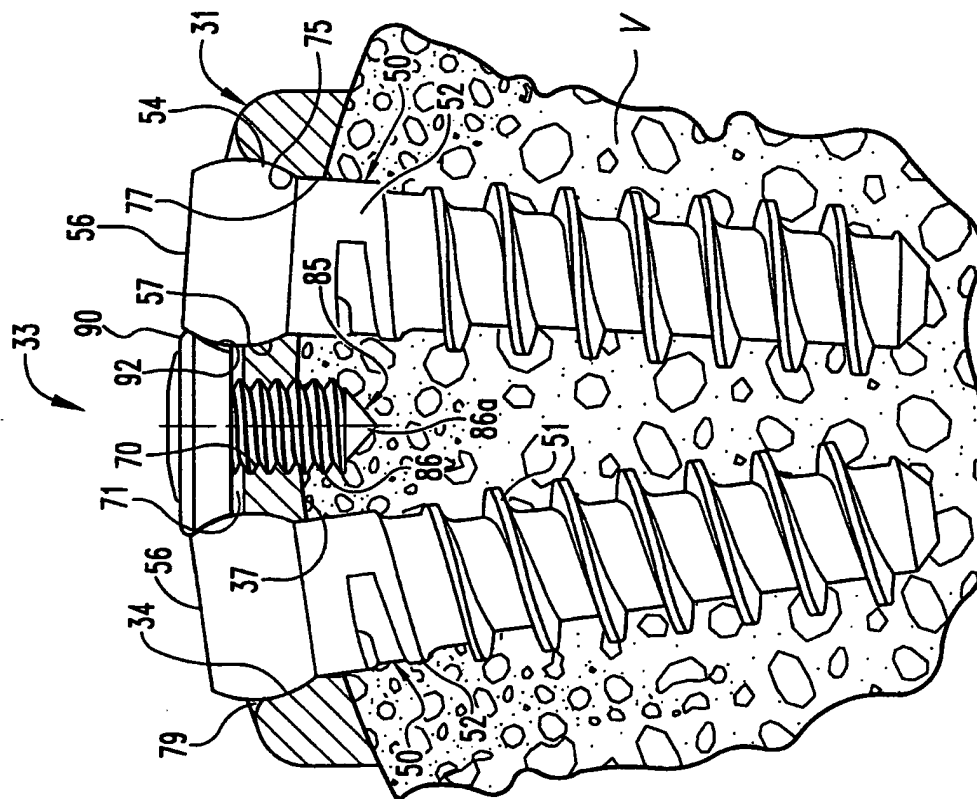
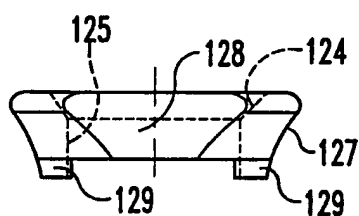
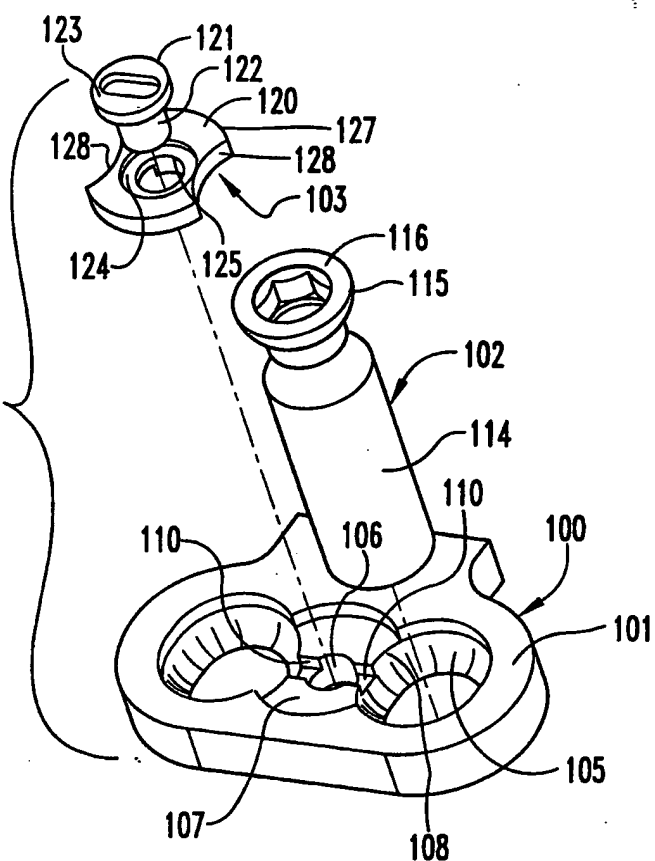
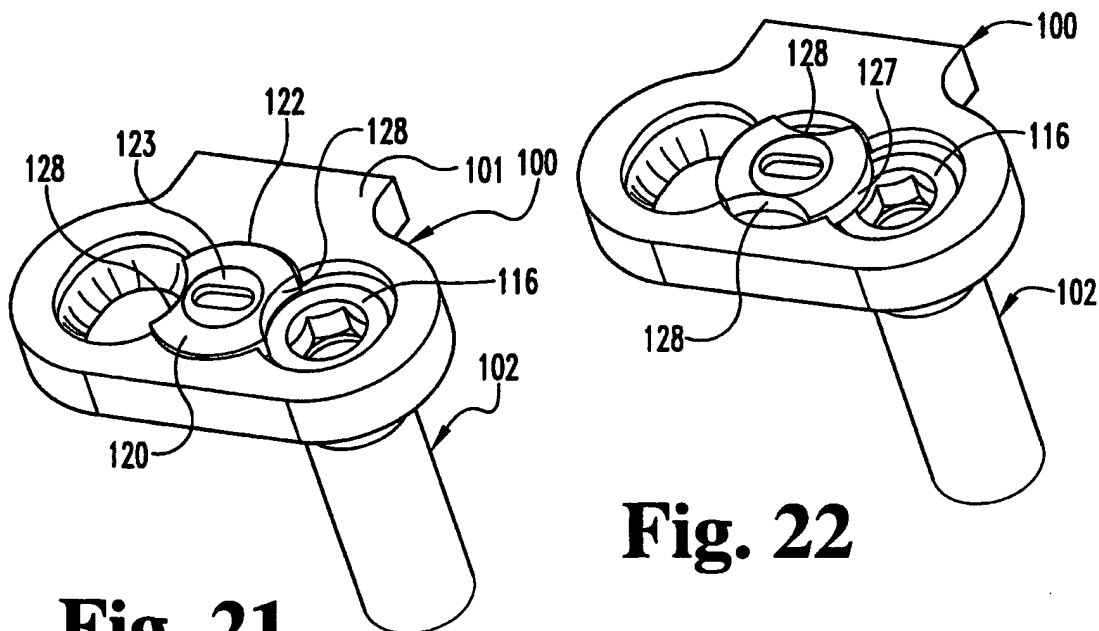


Fig. 18

**Fig. 20**



**Fig. 23**



**Fig. 22**

**Fig. 21**

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